



January 20, 2011

Re: Detergents for Reprocessing of Olympus Surgical Equipment

Dear Health Care Professional:

The purpose of this letter is to provide information on the detergents recommended for reprocessing of Olympus surgical equipment manufactured by Olympus Winter & Ibe (OWI). Please refer to the back page of the Olympus Product Specific Instruction Manual to determine if the product was manufactured by OWI.

This information is intended to clarify and supplement the instructions provided in the Olympus Endoscopy System Guide and Product Specific Instruction Manual. If the information provided in the Product Specific Instruction Manual differs from that provided in the Olympus Endoscopy System Guide, follow the instructions provided in the Product Specific Instruction Manual.

Selecting a Reprocessing Agent

- Olympus surgical devices are compatible with neutral pH and alkaline detergents (pH 11 or less in the working solution) that are formulated for cleaning medical devices. However, the efficacy of the cleaning process may only be validated with a specific type (i.e. alkaline or enzymatic) of detergent. Follow the instructions for use provided in the Product Specific Instruction Manual to identify the validated detergent type.
- The specific cleaning or disinfection agent chosen by your institution should be determined by national and local guidelines, as well as your facility's infection control department.

Manual Cleaning

- Remove persistent debris with a neutral pH or alkaline cleaning agent that has been verified and approved by its manufacturer for cleaning medical endoscopes. Make sure to follow the instructions of the cleaning agent's manufacturer. Avoid acidic agents.
- Do not immerse instrumentation for longer than the time specified by the cleaning agent's manufacturer, but not exceeding 60 minutes. Refer to the instructions of the cleaning agent's manufacturer for immersion time.

Automated Cleaning

- Use only detergents that are certified by their manufacturers as safe for surgical instrument cleaning. Make sure not to exceed the specifications provided by the detergent manufacturer.
- Use enzyme-based agents with neutral pH or alkaline agents with a pH value of up to 11 in the working solution. However, the efficacy of the cleaning process may only be validated with a specific type (i.e. alkaline or enzymatic) of detergent. Follow the instructions for use provided in the Product Specific Instruction Manual to identify the validated detergent type. Avoid acidic agents.

OLYMPUS AMERICA INC.

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WARNING!

Infection Control Risk with Cleaning Agents

Use only verified cleaning agents which feature validated processes in accordance with national and local guidelines. There is an infection control risk when using insufficient cleaning agents.

The Endoscopy System Guide for OWI products is currently being updated and will be consistent with the instructions provided above. If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bradley J. Catalone", with a stylized flourish extending to the right.

Bradley J. Catalone
Director of Clinical Affairs